IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327 MDL 2327**
THIS DOCUMENT RELATES TO: *All Wave 3 cases listed in Exhibit A to Defendants' motion*	**JOSEPH R. GOODWIN U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF BRUCE ROSENZWEIG, M.D.

The Plaintiffs respectfully request that this Court deny Defendants' motion that seeks to limit Dr. Rosenzweig's general opinions—except to the extent that certain points, on which the Court has previously ruled in Ethicon's favor, are uncontested, as noted below.

INTRODUCTION

Defendants' motion to exclude Dr. Bruce Rosenzweig offers a litany of arguments that the Court has already addressed—in some cases many times. Ethicon has provided no new evidence or arguments that would support a change by the Court as to the many areas on which the Court has denied similar arguments. Meanwhile, Plaintiffs are not asking the Court to reconsider prior rulings where the Court has already evaluated all of the relevant information and made its decision—as noted in Sections V and VII. Plaintiffs are only asking for further consideration on two issues, regarding laser-cut mesh and mini-slings. The Court previously stated that it did not have enough information to rule as to whether Dr. Rosenzweig had the clinical experience to opine about the effects of laser-cut mesh, so this brief provides additional information. And Plaintiffs are respectfully requesting reconsideration of the Court's prior

ruling prohibiting Dr. Rosenzweig from opining about the impact of the TVT-Abbrevo's shorter length. There is sufficient evidence to support this claim, including the omission of mini-slings from society statements that support Ethicon's full-sized mesh products.

Dr. Rosenzweig's opinions have been vetted as much as any expert's in the various MDLs. This Court has consistently found him well qualified to testify on a wide variety of topics. In fact, this Court's order in *Huskey* denying Defendants' motion for a new trial cited extensively to Dr. Rosenzweig's testimony as having provided sufficient support for the plaintiff's claims, in several different areas. *See Huskey v. Ethicon, Inc.*, No. 2:12-CV-05201, 2015 WL 4944339, at **4-8 (S.D.W. Va. Aug. 19, 2015) (discussing Dr. Rosenzweig's testimony that the TVT-O product shrinks and deforms, causing a foreign body reaction; that the heavyweight Prolene mesh was not suitable for implantation in the human body; and that the warnings in the TVT-O IFU about "transient" groin pain were insufficient).

Dr. Rosenzweig is a pelvic-floor surgeon based in Chicago. Defendants have described Dr. Rosenzweig as a "[v]ery skilled pelvic floor surgeon,"[1] and Ethicon even invited Dr. Rosenzweig for special training in Belgium on how to implant the TVT-O device.[2] Dr. Rosenzweig is an assistant professor of Obstetrics and Gynecology at Rush University Medical Center. Previously, he had fellowships at the State University of New York at Syracuse, and at UCLA. He started a urogynecology program at the University of Illinois-Chicago, and he has performed more than one thousand surgeries in the pelvic floor, including more than 300 surgeries to address complications associated with synthetic mesh products. Dr. Rosenzweig has

[1] Ethicon surgeon database, attached to Wave 1 response as Exhibit A, at Line 90. Many of the exhibits to this response were attached to Plaintiffs' Wave 1 response, which was Docket No. 2163, or to Defendants' Wave 1 motion, which was Docket No. 2047. For those exhibits, Plaintiffs will cite to the prior filings, as Defendants did with their motion. For all other exhibits, Plaintiffs will attach the exhibit and give it a number instead of a letter to avoid confusion. An Index of the attached exhibits appears at the end of this brief.

[2] Rosenzweig *Mullins* TVT Report, Ex. C-1 to Docket No. 2047, at 3.

also published numerous articles and given numerous lectures on the treatments of urinary incontinence and pelvic organ prolapse.[3]

This Court has written, in various *Daubert* orders, that "Dr. Rosenzweig has demonstrated extensive knowledge of and experience with the process of polypropylene mesh degradation in the body"; that "[a]lthough Dr. Rosenzweig has never designed vaginal mesh devices, he has considerable familiarity with their structure and use"; that "Dr. Rosenzweig received thorough training on the implantation of sling products in pelvic repair"; and that "although Dr. Rosenzweig is not a toxicologist, he stated that he regularly encounters cytotoxicity in his practice, including in women who have polypropylene mesh implants," *Wilkerson v. Boston Scientific Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at **5-6 (S.D. W. Va. May 5, 2015); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 707 (S.D. W. Va. 2014). As a result, this Court "has considered Dr. Rosenzweig as a general causation expert [several] times in the past, and on each occasion [the Court has] admitted his general causation testimony on the properties of polypropylene mesh." *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 565 (S.D. W. Va. 2014), *as amended* Oct. 29, 2014.

This Court should conclude, as it has in the past, that Dr. Rosenzweig is well qualified to offer the general opinions stated in his reports, and that his combination of clinical observations and intense scientific study have formed the foundation of reliable opinions. Based on Dr. Rosenzweig's surgical practice, his academic study, and his years of study associated with this litigation, Dr. Rosenzweig is one the most knowledgeable people in the world on the use of pelvic mesh products to treat SUI.

[3] *Id.* at 2-3.

LEGAL STANDARDS

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). This aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

ARGUMENT

The Court should reject the large majority of Ethicon's arguments for exclusion, as described below. The issues are addressed in the order presented by Ethicon.

I. Dr. Rosenzweig's opinion about that Ultrapro mesh—or a similar product—would be a safe and effective alternative is reliable, as this Court has held.

Ethicon's first point heading suggests a broad exclusion of all of Dr. Rosenzweig's opinions regarding safer alternative designs, but the argument does not remotely support such a broad exclusion. In essence, Ethicon is attacking Dr. Rosenzweig's opinion that Ultrapro mesh, or a similar lighter-weight product, would be a safer alternative to Defendants' devices.

The Court has already rejected Ethicon's attacks on this opinion, holding that Dr. Rosenzweig's opinion as to Ultrapro was reliable and supported by sufficient scientific studies. *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4500765, at *3 (S.D. W. Va. Aug. 26, 2016).

Ethicon's first argument to try to change that result is nonsensical. Ethicon argues simply that because Ultrapro has never been actually placed onto the market, it could not be a feasible alternative design. Clearly, Ethicon should not benefit from its own failure to bring the product to market, and, as this Court previously noted, Dr. Rosenzweig relies on scientific evidence in concluding that Ultrapro—or another SUI product using similar mesh—could be safe and effective. *See id.*

Ethicon's second argument also tries to create a non-existent legal standard, arguing that a safer alternative design must be equally effective. By Ethicon's logic, a device that is 1% less effective and 50% safer could not be a "safer alternative design." That is a question of state law that cannot be answered in the abstract. Ethicon cites to no particular state law that advances such a requirement. Generally, state law turns on issues such as whether the product is unreasonably dangerous, as measured by a risk-utility test, a consumer expectations test, or another standard such as West Virginia's requirement that the product be "reasonably safe for its intended use." *See Mullins v. Ethicon, Inc.*, 117 F. Supp. 3d 810, 812 (S.D. W. Va. 2015).

Defendants also rely, once again, on a wholly distinguishable case in citing *Conklin v. Novartis Pharmaceuticals Corp.*, Civ A. No. 9:11CV-178, 2012 WL 4127295 (E.D. Tex. Sept. 18, 2012). In *Conklin*, an expert was excluded for having an opinion with a logical fallacy that the court described as follows:

> **Premise:** Studies show that a certain regimen of Zometa helps treat cancer-related bone conditions, but may cause ONJ.

> **Premise:** Other studies show that less Zometa will result in less ONJ.
>
> **Conclusion:** A regimen using less Zometa will help treat cancer-related bone conditions.

Id. at *9. In other words, the expert opined that because safety is better, efficacy is necessarily better. Nowhere has Dr. Rosenzweig made such a claim. Rather, he said that a product similar to Ultrapro would change the risk profile so as to affect the risk-utility balance.[4] Unlike in *Conklin*, there are studies that support the efficacy of using a lighter-weight, larger-pore, absorbable mesh to treat SUI.

The argument also fails because it attacks the **conclusion** that using a lighter-weight, larger-pore mesh such as Ultrapro would be a safer and effective alternative design. This argument does not go to Dr. Rosenzweig's methodology. Generally, the *Daubert* inquiry is focused on methods, not on conclusions. *See Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998) (stating that courts should focus on expert witnesses' "principles and methodology, not on the conclusions that they generate"). The sole exception is that an opinion is unreliable if there is "simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

Here, Defendants fail to demonstrate any analytical gap between Dr. Rosenzweig's reasoning and his conclusion. Mainly, they contest his opinion that Ethicon should have used a lighter-weight, larger-pore mesh to treat SUI, as it did in using the lightweight "Ultrapro" mesh to treat hernias. Defendants claim there are no studies supporting the efficacy of Ultrapro—or a similar product—for treatment of SUI. (Def. Memo. at 3). However, as Defendants concede, the issue has been studied. The Okulu study used Ultrapro mesh as a sling to treat SUI, and a

[4] Bruce Rosenzweig Sept. 22, 2015 Deposition, attached as Exhibit 1, at 154:14-155:2.

three-year study showed that it was effective.[5] The study concluded: "Ultrapro mesh can be used in sling surgery owning to its higher success rates, and lower vaginal and urethral extrusion and de novo urgency rates, which have also been shown in clinical studies."[6]

Of course, the Okulu study is not the sole basis for Dr. Rosenzweig's opinion that Ethicon should be using lighter-weight, larger-pore mesh. Using his TVT-O report as an example, Dr. Rosenzweig notes that as early as the late 1990s, Ethicon discussed internally the benefits of using lighter-weight, larger pore mesh in the pelvic floor.[7] Dr. Holste testified that Ethicon has developed lighter-weight larger pore meshes to try to limit complications such as foreign body reaction, erosions, and contraction of the mesh.[8] His report further discusses how Ethicon understood the benefits of using larger-pore, lighter-weight meshes to treat SUI, but was concerned about losing the marketing value of studies supporting the original TVT.[9]

There are other studies that support the use of lighter-weight, larger pore meshes to treat SUI. The Moalli study tested Ethicon's Gynemesh and two lower-weight higher-porosity meshes, including Ultrapro.[10] One of its primary conclusions was that the degree of inflammatory response and scaring increases with a decrease in pore size.[11] A study on the T-sling, an absorbable mesh product designed to treat SUI, discussed how Prolene mesh is subject

[5] Okulu, et. al, *Use of three types of synthetic mesh material in sling surgery: A prospective randomized clinical trial evaluating effectiveness and complications*, SCANDINAVIAN J. OF UROLOGY, 2013; 47:217-224, Exhibit B to Dkt. No. 2163.
[6] *Id.* at 217.
[7] Rosenzweig Ramirez TVT-O Report, Ex. C-5 to Dkt. No. 2047, at p. 13 & n.6.
[8] *Id.* at 24.
[9] *Id.* at 64.
[10] Brown BN, et al., *Characterization of the host inflammatory response following implantation of prolapse mesh in rhesus macaque*, Am. J. of Obstetrics & Gynecology (2015), Exhibit C to Dkt. No. 2163, at p. 3.
[11] *Id.* at p. 14.

to curling and shrinkage, leading to urinary retention or urethral erosion.[12] The T-sling, similar to Ultrapro in that it incorporates absorbable mesh, achieved a perfect cure rate in treating SUI.[13] The concept of studying absorbable mesh for treatment of SUI is not new. A 1983 study tested an absorbable mesh with 21 women, and 20 achieved a cure of their SUI, while just one had a relapse after two months.[14] So, to the extent that some state's law might require it, there is ample scientific evidence to support the claim that a lighter-weight, absorbable mesh such as Ultrapro would be effective, in addition to being safer.

In his deposition, Dr. Rosenzweig explained that while Okulu was the only study to specifically study Ultrapro mesh to treat SUI, "there are multiple studies that show why it's advantageous in the pelvic floor to have a larger pore, lighter weight, less stiff mesh because of processes that can lead to cell death, that lead to smooth muscle dysfunction, that lead to more erosions, that lead to more complications."[15] There is no "analytical gap" between the information that Dr. Rosenzweig has considered and the opinions he is offering. Thus, the Court should reject Defendants' argument is that the available data are insufficient to support Dr. Rosenzweig's conclusions.

II. Dr. Rosenzweig has separate criticisms of Ethicon's mechanically cut and laser-cut mesh. His opinions are supported and are not contradictory.

The Court should also reject Ethicon's argument regarding the cut of the mesh. As this Court is aware, Dr. Rosenzweig has different criticisms of the laser-cut and mechanically cut

[12] Jeffrey Blitstein, M.D., et al., *A Novel Composite Sling for the Treatment of Stress Urinary Incontinence: First Clinical Experience*, International Congress of the European Hernia Society, presented June 22, 2001. Exhibit D to Dkt. No. 2163.
[13] *Id.* at p. 1 (Abstract).
[14] Stefan Finau, Goran Soderberg, *Absorbable Polyglactin Mesh for Retropubic Sling Operations in Female Stress Urinary Incontinence*, Gynecol. Obstet. Invest. 16:45-50 (1983), at p. 48. Exhibit E to Dkt. No. 2163.
[15] Rosenzweig Sept. 22, 2015 Dep., Ex. 1 hereto, at 175:7-176:9.

mesh, each of which create unique problems. In his deposition for the *Perry* state court trial, Dr. Rosenzweig explained these opinions:

> Mechanical-cut mesh ropes, curls, frays. Once you stretch it to a greater than 10 to 15% elongation, it can undergo permanent elongation. You can lose pore size. Laser-cut mesh is stiff and therefore you get the properties of stress shielding which increases erosion, incontinence and pain.[16]

Dr. Rosenzweig has always believed that both kinds of edges have unique problems. Also, the nature of the product can make a difference. As Ethicon's own documents reveal, the stiffness problem—the major issue with laser-cut mesh—is particularly significant with a smaller product. As stated in one Ethicon internal document, authored by Dan Smith: "The short laser cut mesh does not stretch the same as a full length mechanically cut TVT-O, or even as much as … full length LC TVT-O meshes."[17]

Regardless, alleged inconsistencies in testimony are a basis for cross-examination, not a basis for exclusion. *See In re Ethicon*, 2016 WL 4500765, at *7 ("To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence."). *See also In re Avandia Mktg., Sales Practices & Products Liab. Litig.*, No. 2007-MD-1871, 2011 WL 13576, at *9 (E.D. Pa. Jan. 4, 2011) (holding that Dr. Elliott Brinton could testify that Avandia was unsafe, even though he had previously tried to persuade a state board that the drug was safe enough to be left on the state's formulary, because "this criticism of Dr. Brinton goes to his credibility, and not to his methods").

[16] Rosenzweig *Perry* Dep., portions attached hereto as Exhibit 2, at 179:4-12.
[17] Dan Smith Memo, *Things to consider as we assess next steps for a next generation sling*, attached hereto as Exhibit 3, at ETH.MESH.09911297.

As to mechanically cut mesh specifically, Ethicon's argument is short and unavailing. As Dr. Rosenzweig testified in the Lewis trial, there is evidence in the scientific literature of pain and dyspareunia being caused by particle loss from the mechanically cut mesh.[18]

On the issue of laser-cut mesh, the Court previously indicated that Dr. Rosenzweig's clinical experience could support his opinions, but the Court reserved ruling as to his clinical experience. Ethicon suggests that Dr. Rosenzweig has no clinical experience, but its argument is misleading. He may be unsure about whether he has **implanted** laser-cut devices, but that is because he has long stopped implanting mesh devices due to the complications he was seeing in his patients. However, he regularly performs surgery to **remove** mesh devices due to complications, and he has explanted a substantial number of laser-cut mesh slings. In doing so, he has seen the complications discussed in his report, including pain, damage to the urethra, and damage to the bladder.[19]

Thus, Dr. Rosenzweig's clinical experience supports his opinion, contrary to Ethicon's claims, but that is not the sole support. He also relies on Ethicon internal documents that describe the complications associated with the laser-cut mesh. And, as noted in Ethicon's own brief, the one study that compared the types of mesh found higher rates of erosions with the stiffer, laser-cut mesh.[20] It is worth noting that, as Dr. Rosenzweig also testified, the reason that the comparison has been so poorly studied is that, despite the significant differences between the two products, Ethicon has marketed laser-cut and mechanically cut mesh to doctors as being the same.[21]

For these reasons, the Court should conclude that Dr. Rosenzweig's opinions as to the complications with mechanically cut and laser-cut mesh are reliable.

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[18] *Lewis v. Ethicon, Inc.*, Day 2 Tr., Exhibit L to Dkt. No. 2163, at pp. 85:18-87:14; 99:9-100:19 .
[19] Affidavit of Bruce Rosenzweig, Oct. 7, 2016, attached hereto as Exhibit 4, at ¶¶ 4-6.
[20] Rosenzweig 9-22-15 Dep., Ex. 1 hereto, at 200:23-201:5.
[21] *Id.* at 202:15-203:2.

III. As this Court has recognized many times, Dr. Rosenzweig is well qualified to testify about the warnings and instructions given with Ethicon's products.

It is, frankly, absurd, that Ethicon is once again asserting that Dr. Rosenzweig is unqualified to opine about warnings, after the Court has held that he is many times. While Plaintiffs are mindful of the Court's admonition not to rely solely on its prior rulings, it seems implausible that an expert who has many times been declared to be qualified on an issue would somehow **lose** his qualifications. On the question of warnings, this Court has previously noted Dr. Rosenzweig's experience in consulting on the creation of Instructions for Use for a medical device. The Court then listed additional factors in allowing this testimony:

> Dr. Rosenzweig also testified that he served on another company's scientific advisory committee that worked on similar documents. In his expert report, Dr. Rosenzweig states that he has reviewed "numerous" IFUs for a "variety of products including mesh products in order to understand the proper way to use the device and to gain knowledge about the complications and adverse events associated with the device." Further, as a urogynecologist, Dr. Rosenzweig is qualified to opine about the risks of the TVT–O and pelvic mesh surgery and whether those risks were adequately expressed on the TVT–O's IFU. I therefore **FIND** that Dr. Rosenzweig is qualified to testify generally on the adequacy of the TVT–O's product warnings and marketing materials.

Huskey v. Ethicon, Inc., 29 F. Supp. 3d 691, 704 (S.D. W. Va. 2014) (citations omitted). Nothing has changed that should alter the Court's rulings as stated in *Huskey* and in several additional cases. *See, e.g.*, *Wilkerson v. Boston Sci. Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at *8 (S.D. W. Va. May 5, 2015).

IV. The Court should once again allow Dr. Rosenzweig to opine about the properties of the mesh, and about the effects of cytotoxicity.

In another rehashed argument, Ethicon claims that Dr. Rosenzweig should not be permitted to opine as to degradation and other properties of the mesh. Again, this Court has rejected this same argument as to Dr. Rosenzweig numerous times, including in Ethicon Wave 1. Ethicon's claim is that Dr. Rosenzweig cannot connect these problems with clinical impacts.

This Court held that—even if true—such assertions were not relevant to the admissibility of Dr. Rosenzweig's testimony. The Court wrote as follows:

> I reject this argument. A single expert need not provide all the pieces of the puzzle for their testimony to be useful to the jury in determining the ultimate issues in the case. *See, e.g.*, *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 710 (S.D. W. Va. 2014) (rejecting a similar argument). Dr. Rosenzweig's testimony is a relevant step towards establishing general causation. Nor does his alleged inability to connect degradation, fraying, particle loss, and cytotoxicity to specific complications undermine the reliability of his testimony that these phenomena occur. Ethicon's Motion is **DENIED** on these matters.

In re Ethicon, 2016 WL 4500765, at *4.

It is also inaccurate for Ethicon to suggest that Dr. Rosenzweig cannot connect issues such as degradation to clinical outcomes. His expert report states that he has "personally seen mesh that is broken, cracked, brittle and look different from when it came out of the package."[22] Dr. Rosenzweig also explained in detail the problems that are caused by degradation, including but not limited to: greater foreign body reaction, enhanced inflammatory response, and excessive scarring, which then leads to additional complications.[23]

There are also scientific studies and internal documents that support Dr. Rosenzweig's opinions on the impact of degradation. For instance, a recent study by Imel, et al., concludes that "[d]egradation causes surface cracking, mesh contraction, loss of mass, embrittlement, decreased melting temperature, foreign body reactions and reduced compliance of the material."[24] An Ethicon document reveals concern that "small particles are released that migrate through the vaginal wall causing pain."[25] A study on the T-sling, an absorbable mesh product designed to

[22] Rosenzweig Ramirez TVT-O Report, Ex. C-5 to Dkt. No. 2047.
[23] *Id.*
[24] Imel, A., et al., *In Vivo Degradation of Polypropylene Pelvic Mesh, Biomaterials* (2015), Exhibit I to Dkt. No. 2163, at p. 3.
[25] *Pelvic Floor Repair – Surgeon's Feed-back on Mesh Concept*, at ETH.MESH.05644164, Exhibit J to Dkt. No. 2163.

treat SUI, discussed how Prolene mesh curls and shrinks, leading to urinary retention or urethral erosion.[26] Thus, Ethicon's argument should be rejected for both legal and factual reasons.

This Court has also, on several occasions, permitted Dr. Rosenzweig to opine about cytotoxicity, which is cell death. *See, e.g.*, *Huskey*, 29 F. Supp. 3d at 705; *In re: Ethicon Inc.*, 2016 WL 4500765, at *5 ("To the extent that Ethicon believes cytotoxicity is not clinically significant, Ethicon may cross-examine Dr. Rosenzweig on that issue."). Ethicon cites only the *Huskey* ruling—ignoring the Court's Wave 1 ruling—and claims that Dr. Rosenzweig has made certain new statements. But those statements came before the Court's recent ruling. In addition, as previously discussed, Dr. Rosenzweig did not concede anything in the cited deposition:

> Q. Are there any clinical studies assessing TVT in women with stress urinary incontinence that reports that cytotoxicity of the mesh is a cause of their – any reported complications?
>
> A. Erosion is a sign of cytotoxicity.[27]

Cytotoxicity is simply a fancy name for cell death, and it is something that Dr. Rosenzweig experiences in practice all of the time.[28] The fact that Ethicon has not created a study with that specific focus does not mean that cytotoxicity has no clinical relevance. This aspect of Ethicon's motion should clearly be denied.

V. Testing, adverse event reporting, and training

The Court has previously precluded Dr. Rosenzweig from testifying as to the issues raised in Section V, and Plaintiffs are not contesting those prior rulings at this time. The issues are Ethicon's testing, adverse event reporting, and training.

[26] Jeffrey Blitstein, M.D., et al., Exhibit D to Dkt. No. 2163, at p. 1 (Abstract).
[27] Rosenzweig Sept. 22, 2015 Dep., Ex. 1 hereto, at 256:5-9.
[28] Rosenzweig Dec. 20, 2013 Affidavit, Exhibit K to Dkt. No. 2163, at ¶ 4.

VI. Dr. Rosenzweig's opinion regarding the effect of the mini-sling is supported by Ethicon documents, scientific literature, and society statements that Ethicon regularly relies upon.

Plaintiffs, respectfully request that the Court reconsider its Wave 1 ruling with regard to the impact of the shorter length of the TVT-Abbrevo. The Court did exclude this opinion in Ethicon Wave 1, asserting that Dr. Rosenzweig cites to an Ethicon internal document that does not support his opinion. *In re: Ethicon Inc.*, No. 2327, 2016 WL 4500765, at *5. But the cited document, a memo by Ethicon's Dan Smith, details numerous problems with the TVT-Abbrevo concept, which is described as the "Mini-me" sling in the memo. The first problem mentioned is that "[t]he short laser cut mesh does not stretch the same as full length mechanically cut TVT-O, or even as much as full length LC [laser cut] TVT-O meshes."[29]

The memo also states that the Abbrevo, as a mini-sling, will face similar problems to those that Ethicon had already experienced with the TVT-Secur, another smaller sling.[30] Thus, while Ethicon has not conducted clinical trials with the TVT-Abbrevo, Ethicon's own analysis lends credence to using data on the TVT-Secur to highlight the problems with the TVT-Abbrevo. For instance, in a 2011 article, Dr. Neumann noted the 7.9% dyspareunia rate for the TVT-Secur and wrote that this relatively high rate "might be explained in part by the rigidity and reduced flexibility of the synthetic polypropylene implant because it is laser cut, which tends to result in a stiff tape edge."[31]

Finally, two other points support Dr. Rosenzweig's conclusions regarding the TVT-Abbrevo. First, two of the inventors of the original TVT, Carl G. Nilsson and Christian Falconer, plus the inventor of the TVT-O, Jean de Leval, have all refused to use the laser-cut

[29] Dan Smith memo, Ex. 3 hereto, at ETH.MESH.09911297.
[30] *Id.*
[31] Neuman, et al., *Transobturator vs Single-Incision Suburethral Mini-slings for Treatment of Female Stress Urinary Incontinence: Early Postoperative Pain and 3-Year Follow-up*, J. OF MINIMALLY INVASIVE GYNECOLOGY, Nov.-Dec. 2011, Exhibit N to Dkt. No. 2163, at p. 772.

TVT Abbrevo.[32] Second, the society statements that Ethicon relies so heavily on in this litigation, touting the alleged safety of the TVT products, have omitted mini-slings from their claims that Ethicon's products are the "gold standard."[33] Thus, even organizations that support the use of Ethicon's mesh recognize a distinction that is specifically tied to the length of the sling. For these reasons, the Court should allow Dr. Rosenzweig's testimony that the length of the TVT-Abbrevo sling contributes to the complications that it causes.

VII. Marketing

The Court has previously excluded Dr. Rosenzweig's marketing opinions, and Plaintiffs are not asking for reconsideration of that ruling at this time.

VIII. As this Court has previously recognized, Dr. Rosenzweig is qualified to discuss the substance of the MSDS warning regarding oxidation.

The Court should also reaffirm its prior ruling that permitted Dr. Rosenzweig to testify regarding the Material Safety Data Sheet ("MSDS") for the Prolene used in Ethicon's mesh. As this Court wrote, "[a] urogynecologist does not need to be an expert in crafting MSDS warnings to use the substance of such warnings in forming opinions about how mesh reacts in the human body." *In re: Ethicon Inc.*, 2016 WL 4500765, at *4.

Previously, this Court found it important that Dr. Rosenzweig had opined "that the potential for cytotoxicity is important information that physicians need to know." *Huskey*, 29 F. Supp. 3d at 705. Similarly, as to the MSDS, Dr. Rosenzweig is not planning to analyze the factors that went into the warning itself. His opinions focus on the fact that this warning was

[32] Rosenzweig TVT-Abbrevo Report, Ex. D to Dkt. No. 2047, at 13.

[33] *See* AUGS & SUFU Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence, attached as Exhibit 5, at p. 2, ¶ 3 ("Full-length midurethral slings … have been extensively studied, are safe and effective relative to other treatment options and remain the leading treatment option and gold standard for stress incontinence surgery."). By expressly referring to "[f]ull-length" slings, these societies—which support the use of mesh generally—were putting shorter slings such as TVT-Abbrevo into the basket of "other treatment options."

important information that Ethicon should have made available to physicians.[34] His experience qualifies him to give those opinions, as this Court has recognized.

Ethicon also claims that the MSDS is irrelevant, even though the MSDS warns that polypropylene is incompatible with strong oxidizers such as peroxides, which are readily found in the vagina.[35] As discussed in Dr. Rosenzweig's report, the vaginal area contains significant natural oxidizers, causing a potential bad reaction with the polypropylene.[36] His primary opinions are that the Defendants should have done "clinically relevant testing," and that physicians should have been warned about the danger of placing this polypropylene in an oxidized area.[37] Thus, the MSDS is relevant to his opinions, and relevant to the problems that Ethicon's mesh causes for women.

The Court should allow this opinion, as it did in Wave 1. *In re: Ethicon Inc.*, 2016 WL 4500765, at *4.

IX. Other opinions

In Wave 1, the Court issued a detailed order on the issues raised by Ethicon in Section IX, and Plaintiffs assume the Court will take a similar approach in Wave 3. Plaintiffs will attempt to confine their experts' testimony to the guidelines laid out by the Court with regard to narrative testimony, legal conclusions, and the like. One point worth noting, however, is that the Court excluded—with regard to a different expert—evidence of complications that no plaintiff in the **entire wave** had suffered. Ethicon is now asking for exclusion of complications not suffered by a particular plaintiff. The Court should reserve ruling on that issue, as variances in state law could impact the relevance of such a complication. For instance, a regular complication

[34] Rosenzweig Prosima Report, Ex. G to Dkt. No. 2047, at 36-37.
[35] *Id.* at pp. 4 (summary), 63-64.
[36] *Id.* at 36.
[37] *Id.* at 36-37.

associated with the mesh, such as dyspareunia, would be relevant to a design defect inquiry in a state where the jury is asked to balance the risks and the utility of a particular device—even if that particular plaintiff did not suffer from the common problem.

CONCLUSION

The Court should deny Ethicon's motion, except as to the issues in Sections V and VII where the Court has previously ruled in Ethicon's favor and Plaintiffs are not seeking reconsideration.

Dated: October 11, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on October 11, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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Attorney for Plaintiffs

INDEX OF EXHIBITS

Exhibit 1: Bruce Rosenzweig Sept. 22, 2015 Deposition, full transcript

Exhibit 2: Excerpts of Bruce Rosenzweig Deposition in *Perry v. Luu*, No. S-1500-CV 279123 (Calif. Sup. Ct., Kern County), taken Dec. 15, 2014

Exhibit 3: Dan Smith Memo, "Things to consider as we assess next steps for a next generation sling," at ETH.MESH.09911296-99.

Exhibit 4: Affidavit of Bruce Rosenzweig, Oct. 7, 2016

Exhibit 5: AUGS & SUFU Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence